

IDS 12/14/01

SUBSTITUTE FORM PTO-1449  
(MODIFIED)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.:  
3100-0001.20SERIAL NO.: CIP of  
filed 10/25/01 (Serial  
No. not yet assigned)**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
(Use several sheets if necessary)

(37 CFR 1.98(b))

APPLICANT:  
Bret BERNER et al.FILING DATE:  
Concurrently herewithGROUP:  
Unassigned**U.S. PATENT DOCUMENTS**

EXAMINER INITIALS	CITE NO.	PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
J	AA	4,695,467	9/22/87	Uemura et al.			
J	AB	4,910,021	3/20/90	Davis et al.			
J	AC	5,002,772	3/26/91	Curatolo et al.			
J	AD	5,007,790	4/16/91	Shell			
J	AE	5,425,950	6/20/95	Dandiker et al.			
J	AF	5,582,837	10/10/96	Shell			
J	AG	5,738,874	4/14/98	Conte et al.			
J	AH	5,783,212	7/21/98	Fassihi et al.			
J	AI	5,840,332	11/24/98	Lerner et al.			
J	AJ	5,891,474	4/6/99	Buseti et al.			
J	AK	5,945,125	8/31/99	Kim			
J	AL	5,972,389	10/26/99	Shell et al.			
J	AM	6,027,748	2/22/00	Conte et al.			
J	AN	6,093,420	7/25/00	Baichwal			
J	AO	6,120,803	9/19/00	Wong et al.			
J	AP	6,221,395	4/24/01	Maggi et al.			9/1/98

**OTHER DOCUMENT — NONPATENT LITERATURE DOCUMENT**

EXAMINER INITIALS	CITE NO.	INCLUDE NAME OF AUTHOR, TITLE OF ARTICLE (IF APPROPRIATE), TITLE OF PUBLICATION, DATE, PAGE(S), VOLUME-ISSUE NUMBER(S), PUBLISHER, AND PLACE OF PUBLICATION
J	AQ	Katori et al. (1995), "Estimation of Agitation Intensity in the GI Tract in Humans and Dogs Based on <i>in Vitro/in Vivo</i> Correlation," <i>Pharmaceutical Research</i> 12(2):237-243.

EXAMINER SIGNATURE:

DATE CONSIDERED:

9/04

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

125 12/18/01

Atty Dkt No. 3100-0001.20

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PATENT NO.	ISSUE DATE	PATENTEE
4,695,467	9/22/87	Uemura et al.
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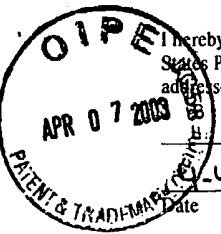
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OTHER DOCUMENT
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This Information Disclosure Statement is not intended as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any of the above references constitutes prior art to the present application within the meaning of 35 USC § 102.

125 4/7/03

Atty Dkt No. 3100-0001.20  
PATENT



I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, Washington, DC 20231" on

April 4, 2003

10-4-03

*Mary O'Malley*  
Signature

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In Re Application of:

Bret BERNER et al.

Confirmation No.: 5481

Serial No.: 10/024,932

Group Art Unit: 1615

Filing Date: December 18, 2001

Examiner: Unassigned

Title: GASTRIC RETENTIVE ORAL DOSAGE FORM WITH RESTRICTED DRUG RELEASE IN THE LOWER GASTROINTESTINAL TRACT

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**SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
Washington, DC 20231

Sir:

This is a Second Supplemental Information Disclosure Statement submitted for the Examiner's consideration. Applicants respectfully request that the Examiner review and make of record the references identified below.

PTO-1449 forms listing the references accompany this paper. Applicants would appreciate the Examiner's initialing and returning the forms to indicate that the references have been reviewed and made of record. The references are as follows:

U.S. PATENT DOCUMENTS		
Document No.	Issue Date or Publication Date	Name of Patentee or Applicant
4,434,153	2/28/84	Urquhart et al.
4,690,824	9/1/87	Powell et al.
4,748,023	5/31/88	Tamás et al.
4,786,503	11/22/88	Edgren et al.
4,839,177	6/13/89	Colombo et al.
4,851,232	7/25/89	Urquhart et al.
4,865,849	9/12/89	Conte et al.
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5,085,865	2/4/92	Nayak
5,213,808	5/25/93	Bar-Shalom et al.
5,232,704	8/3/93	Franz et al.
5,393,765	2/28/95	Infeld et al.
5,422,123	6/6/95	Conte et al.

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5,472,708	12/5/95	Chen
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5,508,040	4/16/96	Chen
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5,736,159	4/7/98	Chen et al.
5,780,057	7/14/98	Conte et al.
5,811,126	9/22/98	Krishnamurthy
5,837,379	11/17/98	Chen et al.
5,840,329	11/24/98	Bai
5,861,173	1/19/99	Nishioka et al.
5,897,874	4/27/99	Stevens et al.
5,916,595	6/29/99	Chen et al.
6,033,685	3/7/00	Qiu et al.
6,207,197	3/27/01	Illum et al.
6,261,601	7/17/01	Talwar et al.
6,340,475	01/22/02	Shell et al.
6,368,628	4/9/02	Seth
6,451,808	9/17/02	Cowles
6,488,962	12/3/02	Berner et al.
2001/0018070	8/30/01	Shell et al.
Serial No. 09/425,491	Filed 10/22/99	Shell et al.
Serial No. 10/029,134	Filed 10/25/01	Gusler et al.
Serial No. 10/045,823	Filed 11/6/01	Shell et al.
Serial No. 10/066,146	Filed 2/1/02	Lim et al.
Serial No. 10/152,914	Filed 5/20/02	Fara et al.

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WO 98/55107 A1	12/10/98	PCT
WO 00/23045 A1	4/27/00	PCT
WO 00/38650 A1	7/6/00	PCT

IDS 4/7/03

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Serial No. 10/024,932

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WO 01/97783 A1	12/27/01	PCT
WO 02/083687 A1	10/24/02	PCT

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Hwang et al. (1998), "Gastric Retentive Drug-Delivery Systems," <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> 15(3):243-284.	
Kim (1995), "Drug Release from Compressed Hydrophilic POLYOX-WSR Tablets," <i>Journal of Pharmaceutical Sciences</i> 84(3):303-306.	
Korsmeyer et al. (1983), "Mechanisms of Solute Release from Porous Hydrophilic Polymers," <i>International Journal of Pharmaceutics</i> 15:25-35.	
Maggi et al. (2000), "High Molecular Weight Polyethylene Oxides (PEOs) as an Alternative to HPMC in Controlled Release Dosage Forms," <i>International Journal of Pharmaceutics</i> 195:229-238.	
Rao et al. (1988), "Swelling Controlled-Release Systems: Recent Developments and Applications," <i>International Journal of Pharmaceutics</i> 48:1-13.	
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Siepmann et al. (1999) "A New Model Describing the Swelling and Drug Release Kinetics from Hydroxypropyl Methylcellulose Tablets," <i>Journal of Pharmaceutical Sciences</i> 88(1):65-72.	
Yang et al. (1996), "Zero-Order Release Kinetics from a Self-Correcting Floatable Asymmetric Configuration Drug Delivery System," <i>Journal of Pharmaceutical Sciences</i> 85(2):170-173.	

This Second Supplemental Information Disclosure Statement is not intended as a representation that a search has been made, that additional information material to the



105 1/29/04

Atty Dkt No. 3100-0001.20  
PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In Re Application of:

Bret BERNER et al.

Confirmation No.: 5481

Serial No.: 10/024,932

Group Art Unit: 1615

Filing Date: December 18, 2001

Examiner: Edward J. WEBMAN

Title: GASTRIC RETENTIVE ORAL DOSAGE FORM WITH RESTRICTED DRUG RELEASE IN  
THE LOWER GASTROINTESTINAL TRACT

**RESUBMITTED INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia

Sir:

Further to the Examiner's request in the Office Action of September 29, 2003, the Information Disclosure Statement of December 18, 2001, is resubmitted per the Examiner's request. In the Office Action, the Examiner indicated that the cited references were not available to the Examiner. As the cited references are provided with this paper, applicants respectfully request that the Examiner review and make of record the references identified below.

A PTO-1449 form listing the cited references is also resubmitted for the Examiner's convenience and is attached to this paper. Upon review of the references submitted herewith, applicants respectfully request that the Examiner initial and return a copy of the PTO-1449 to the applicants in order so that applicants will have a written record that the references submitted herewith have been reviewed and made of record. The references are as follows:

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5,007,790	4/16/91	Shell
5,425,950	6/20/95	Dandiker et al.
5,582,837	10/10/96	Shell
5,738,874	4/14/98	Conte et al.
5,783,212	7/21/98	Fassihi et al.
5,840,332	11/24/98	Lerner et al.

U.S. PATENT DOCUMENTS			RECEIVED FEB 05 2004 TECH CENTER 1600/2900
Document No.	Issue Date or Publication Date	Name of Patentee or Applicant	
5,891,474	4/6/99	Busetti et al.	
5,945,125	8/31/99	Kim	
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6,093,420	7/25/00	Baichwal	
6,120,803	9/19/00	Wong et al.	
6,221,395	4/24/01	Maggi et al.	

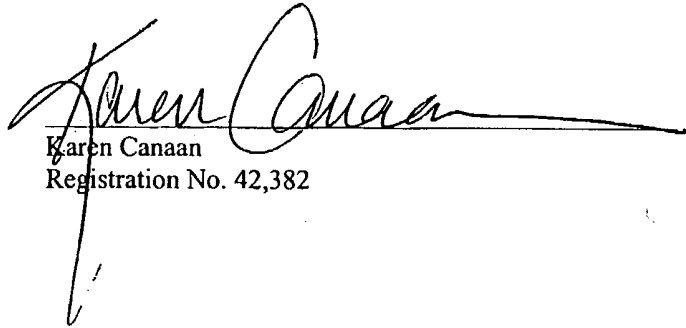
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The attached return post-card indicates that the cited references were mailed along with the Information Disclosure Statement and PTO-1449 on December 18, 2001; accordingly, applicants submit that this resubmission of the Information Disclosure Statement of December 18, 2001, should not be subject to a fee. Nevertheless, if the Office deems that a fee is necessary, then the Office is authorized to charge the appropriate fee to Deposit Account No. 18-0580.

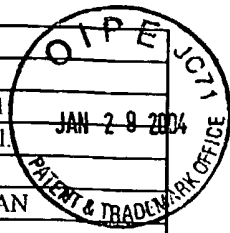
Respectfully submitted,

By:

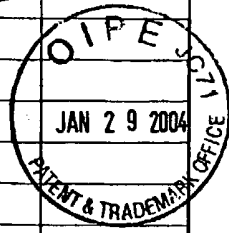
  
Karen Canaan  
Registration No. 42,382

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800 Menlo Avenue, Suite 210  
Menlo Park, California 94025  
(650) 330-0900 Telephone  
(650) 330-0980 Facsimile

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)			<i>Complete if Known</i>		
			Application Number	10/024,932	
			Filing Date	December 18, 2001	
			First Named Inventor	Bret BERNER et al.	
			Art Unit	1615	
			Examiner Name	Edward J. WEBMAN	
Sheet	1	of	3	Attorney Docket Number	3100-0001.20



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OTHER DOCUMENTS — NONPATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), Title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
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Examiner Signature		Date Considered	9/09
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Reynolds et al. (1998), "Polymer Erosion and Drug Release Characterization of Hydroxypropyl Methylcellulose Matrices" <i>Journal of Pharmaceutical Sciences</i> 87(9):1115-1123.	
Siepmann et al. (1999) "HPMC Matrices for Controlled Drug Delivery: A New Model Combining Diffusion, Swelling, and Dissolution Mechanisms and Predicting the Release Kinetics" <i>Pharmaceutical Research</i> 16(11):1748-1756.	
Yang et al. (1996), "Zero-Order Release Kinetics from a Self-Correcting Floatable Asymmetric Configuration Drug Delivery System," <i>Journal of Pharmaceutical Sciences</i> 85(2):170-173.	

This Information Disclosure Statement is not intended as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any of the above references constitutes prior art to the present application within the meaning of 35 USC § 102.

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

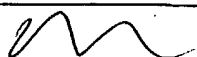
(use as many sheets as necessary)

Complete if Known

Sheet	1	of	3	Application Number	10/024,932
				Filing Date	December 18, 2001
				First Named Inventor	Bret BERNER et al.
				Art Unit	1615
				Examiner Name	Edward J. WEBMAN
				Attorney Docket Number	3100-0001.20

## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	Document No.	Issue Date or Publication Date	Name of Patentee or Applicant of Cited Document	Class	Subclass	Filing Date if Appropriate
J	AW	4,434,153	2/28/84	Urquhart et al.			
J	AX	4,690,824	9/1/87	Powell et al.		1	
	AY	4,748,023	5/31/88	Tamás et al.			
	AZ	4,786,503	11/22/88	Edgren et al.			
	BA	4,839,177	6/13/89	Colombo et al.			
	BB	4,851,232	7/25/89	Urquhart et al.			
	BC	4,865,849	9/12/89	Conte et al.			
	BD	5,064,656	11/12/91	Gergely et al.			
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	CJ	6,451,808	9/17/02	Cowles			10/17/00
J	CK	6,488,962	12/3/02	Berner et al.			6/20/00

Examiner Signature		Date Considered	9/04
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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CM	Serial No. 09/425,491		Shell et al.			10/22/99
CN	Serial No. 10/029,134		Gusler et al.			10/25/01
CO	Serial No. 10/045,823		Shell et al.			11/6/01
CP	Serial No. 10/066,146		Lim et al.			2/1/02
CQ	Serial No. 10/152,914		Fara et al.			5/20/02

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	CS	EP 0795324 A2	9/17/97	Europe			
	CT	WO 96/32097 A1	10/17/96	PCT			
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	CZ	WO 01/97783 A1	12/27/01	PCT			
	DA	WO 02/083687 A1	10/24/02	PCT			


OTHER DOCUMENTS — NONPATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), Title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
	DB	Abrahamsson, et al. (1993), "Absorption, Gastrointestinal Transit, and Tablet Erosion of Felodipine Extended-Release (ER) Tablets," <i>Pharmaceutical Research</i> 10(5):709-714.	
	DC	Apicella et al. (1993), "Poly(ethylene oxide) (PEO) and Different Molecular Weight PEO Blends Monolithic Devices for Drug Release," <i>Biomaterials</i> 14(2):83-90.	
	DD	Columbo et al. (1990), "Drug Release Modulation by Physical Restrictions of Matrix Swelling," <i>International Journal of Pharmaceutics</i> 63:43-48.	
	DE	Davis et al. (1986), "The Effect of Density on the Gastric Emptying of Single- and Multiple-Unit Dosage Forms," <i>Pharmaceutical Research</i> 3(4):208-213.	
	DF	Deshpande et al. (1997), "Development of a Novel Controlled-Release System for Gastric Retention," <i>Pharmaceutical Research</i> 14(6):815-819.	
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	DI	Hwang et al. (1998), "Gastric Retentive Drug-Delivery Systems," <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> 15(3):243-284.	
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J	DM	Rao et al. (1988), "Swelling Controlled-Release Systems: Recent Developments and Applications," <i>International Journal of Pharmaceutics</i> 48:1-13.	
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